UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JANE DOE,

Plaintiff,

v.

MARGARET A. HAMBURG, M.D., *et al.*,

Defendants.

_____/

No. C-12-3412 EMC

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

(Docket No. 36)

Plaintiff Jane Doe has filed suit against the federal government, asserting that her federal constitutional rights have been violated because federal regulations bar a private individual from donating semen to her on an uncompensated basis to use for artificial insemination. Currently pending before the Court is the federal government's motion to dismiss Ms. Doe's first amended complaint ("FAC"). The government argues first that the Court should decline jurisdiction over Ms. Doe's case based on prudential reasons. Second, the government contends that, for each of the asserted constitutional claims, Ms. Doe has failed to state a claim for relief.

Having considered the parties' briefs as well as the oral argument of counsel, the Court hereby **GRANTS** the government's motion.

I. FACTUAL & PROCEDURAL BACKGROUND

In her FAC, Ms. Doe alleges as follows.

Ms. Doe is a woman who resides in Oakland, California. *See* FAC ¶ 11. She wishes to become pregnant. *See* FAC ¶¶ 11, 15. Because she is a lesbian and does not want to engage in sexual intercourse with men, *see* FAC ¶¶ 14, 29, Ms. Doe seeks to become pregnant by artificial

insemination. Ms. Doe does not want to use a traditional semen bank or other commercial establishment for artificial insemination because, *e.g.*, it is expensive, there are limitations on donor selection, donations are often anonymous, and "it is her understanding that she is more likely to become pregnant if she uses fresh donor sperm." FAC ¶¶ 16-17, 34. Accordingly, Ms. Doe seeks "to become pregnant via artificial insemination with semen donated on an uncompensated basis by a private individual, without a medical intermediary such as a semen bank or medical professional."[1] FAC ¶ 2.

Ms. Doe first tried to become pregnant by the above-identified means in or about 2010. In August 2010, Ms. Doe contacted a man by the name of Trent C. Arsenault. *See* FAC ¶ 20. "Mr. Arsenault is a self-described virgin who does not have sexual intercourse . . . ." FAC ¶ 21. Previously, he had "donated semen privately and without compensation to other women who wanted to become pregnant via artificial insemination." *See* FAC ¶ 19. Mr. Arsenault had entered into agreements with these women. *See* FAC ¶¶ 50, 90. Examples of these agreements have been provided by the government as an attachment to the Lee declaration. *See generally* Lee Decl., Ex. A (agreements). The agreements reflect that it was the intent of the semen recipients and the intent of Mr. Arsenault "to sever any and all parental rights and responsibilities of [Mr. Arsenault]." Lee Decl., Ex. A (Agreement ¶ 13). Although not entirely clear, it appears that Ms. Doe entered into a similar agreement with Mr. Arsenault. *See* FAC ¶ 50 (alleging that "Mr. Arsenault is personally known to all women to whom he donates semen, including Ms. Doe, and has entered into agreements with them regarding mutually agreed-upon obligations regarding continued provision of personal and health information").

Ms. Doe does not allege that she had a previous social or intimate relationship with Mr. Arsenault prior to the initiation of the transaction at issue. Ms. Doe merely alleges that, "over the course of numerous conversations," she and Mr. Arsenault "formed an intimate bond and close friendship" before any attempt at conception. FAC ¶ 24. "Mr. Arsenault revealed many intimate,

[1] The FAC indicates that the method of artificial insemination to be used is intracervical insemination ("ICI"), *see* FAC ¶ 16, which involves using a syringe to transfer semen from a specimen cup to the recipient. *See* FAC ¶ 35.

personal details of his life to Ms. Doe and discussed with Ms. Doe his medical history, his health, and his views on the role of a father who helps a woman in a same-sex relationship conceive a child and start a family with her partner." FAC ¶ 24.

Ms. Doe became pregnant from the semen donation made by Mr. Arsenault. Unfortunately, her pregnancy was not carried to term. *See* FAC ¶¶ 26-27. Now, "barring doctor's orders to the contrary, Ms. Doe intends to attempt artificial insemination again with fresh semen from Mr. Arsenault." FAC ¶ 29. There are no specific allegations that Mr. Arsenault is willing to provide Ms. Doe again with semen, although presumably that is the case.

According to Ms. Doe, federal law restricts her from getting pregnant by her desired method of procreation. More specifically, Ms. Doe refers to the Public Health Service Act ("PHSA") and its implementing regulations.

The PHSA provides in relevant part that

> [t]he Surgeon General, with the approval of the Administrator [Secretary of the Department of Health and Human Services], is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

42 U.S.C. § 264(a). "Although [§ 264] does not explicitly grant regulatory authority to the FDA, subsequent changes in the structure of the agencies involved, as well a delegation of authority from the Secretary of the DHHS, make clear that the FDA is empowered to issue regulations under [§ 264]." *Independent Turtle Farmers of La., Inc. v. United States*, 703 F. Supp. 2d 604, 619 (W.D. La. 2010); *see also United States v. Regenerative Scis.*, LLC, No. 10-1327 (RMC), 2012 U.S. Dist. LEXIS 102002, at *19 (D.D.C. July 23, 2012) (stating that, "[a]lthough this section [§ 264] grants this authority to the Surgeon General, it now rests with the FDA").

The regulations promulgated by the FDA include those found in 21 C.F.R. Part 1271. The purpose of Part 1271 "is to create a unified registration and listing system for establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/P's) and to establish donor-eligibility, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/P's." 21 C.F.R. § 1271.1(a). HCT/P's

are defined as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." *Id.* § 1271.3(d). Semen is listed as one example of a HCT/P. *See id.*

Part 1271 is divided into three different subparts to meet the above-stated purpose. Subpart B requires HCT/P manufacturers to register with the FDA. Subpart C requires donors to be screen and tested. Subpart D establishes standard operating procedures to prevent errors and contamination from occurring – *i.e.*, current good tissue practice ("CGTP"). *See* Mot. at 2.

The scope of Part 1271 is defined, in relevant part, as follows:

> *If you are an establishment* that manufactures HCT/P's that are regulated solely under the authority of section 361 of the Public Health Service Act (the PHS Act) [*i.e.*, § 264], this part requires you to register and list your HCT/P's with the Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research and to comply with the other requirements contained in part, whether or not the HCT/P enters into interstate commerce [*e.g.*, the donor eligibility requirements].

Id. § 1271.1(b)(1) (emphasis added). An "establishment" refers to "a place of business under one management, at one general location, that engages in the manufacture of [HCT/P's]." *Id.* § 1271.3(b). An establishment can be an individual. *See id.* § 1271.3(b)(1) (providing that an establishment includes "[a]ny individual, partnership, corporation, association, or other legal entity engaged in the manufacture of [HCT/P's]"). "Manufacture means, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor." *Id.* § 1271.3(e).

Under the PHSA, "[a]ny person who violates any regulation prescribed under section[] [264] . . . shall be punished by a fine of not more than $1,000 or by imprisonment for not more than one year, or both." 42 U.S.C. § 271.

Notably, there are certain exceptions from the requirements imposed by the regulations. For example:

- Directed reproductive donor. An individual who is determined to be an ineligible donor based on the results of the testing or screening required by the regulations is still allowed to donate if he is a "directed reproductive donor." *See* 21 C.F.R. § 1271.65(b)(1)(ii) (providing

that "[a]n HCT/P from a donor who has been determined to be ineligible, based on the results of required testing and/or screening, is not prohibited by subpart C of this part from use for implantation, transplantation, infusion, or transfer under the following circumstances: . . . (ii) The HCT/P consists of reproductive cells or tissue from a directed reproductive donor, as defined in § 1271.3(l)"). A "[d]irected reproductive donor means a donor of reproductive cells or tissue (including semen . . .) to a specific recipient, and who knows and is known by the recipient before donation." *Id.* § 1721.3(l). While a directed reproductive donor is allowed to donate in spite of being "ineligible," he is still required to undergo the testing or screening for eligibility as required by the regulations. Furthermore, a donation that comes from a directed reproductive donor must also be accompanied by certain warnings and records. *See id.* § 1271.65(b)(2).

- Sexually intimate partner. Under the regulations, "[y]ou not required to make a donor-eligibility determination under § 1271.50 *or* to perform donor screening or testing under §§ 1271.75, 1271.80 and 1271.85 for . . . [r]eproductive cells or tissue donated by a sexually intimate partner of the recipient for reproductive use." 21 C.F.R. § 1271.90(a)(2) (emphasis added). The term "sexually intimate partner" or "SIP" is not defined anywhere by the regulations.

In April 2009, *i.e.*, more than a year before Ms. Doe contacted Mr. Arsenault about semen donation, Mr. Arsenault registered his residence as an HCT/P establishment that recovers and distributes semen.[2] *See* FAC, Ex. 2 (Agency Decision at 2). More than a year later, between August 27 and September 16, 2010, the FDA conducted an inspection of Mr. Arsenault's establishment. *See* FAC, Ex. 2 (Agency Decision at 2).

Based on the investigation, the FDA's Center for Biologics Evaluation and Research ("CBER") issued an order to cease manufacturing HCT/Ps to Mr. Arsenault on November 1, 2010. *See* FAC ¶ 48 & Ex. 1 (CBER order); *see also* 21 C.F.R. § 1271.440(a)(3) (allowing the agency to

[2] Ms. Doe's complaint on its face does not mention the fact that Mr. Arsenault registered as an establishment. However, the agency decision that barred Mr. Arsenault from making semen donations absent compliance with Part 1271 makes reference to this fact. Also, Ms. Doe did not dispute this fact at the hearing, although she suggested that the registration was not voluntary.

serve on an establishment an order to cease manufacturing until compliance with the regulations has been achieved). The order seems to apply to Mr. Arsenault only as an establishment.[3] *See, e.g.*, FAC, Ex. 1 (CBER order) (noting that the FDA "conducted an inspection of your Establishment").

According to the CBER, Mr. Arsenault had "failed to adhere to the donor screening, testing, and eligibility requirements that apply to him as a directed donor for semen donations that were recovered and distributed to approximately 46 different recipients between December 2006 and September 2010." FAC, Ex. 2 (Agency Decision at 6-7). "CBER also found that Mr. Arsenault failed to adhere to related recordkeeping requirements." FAC, Ex. 2 (Agency Decision at 7).

In response to the CBER's order to cease manufacturing, Mr. Arsenault sought an administrative hearing and made several submissions to the agency. The CBER in turn asked that Mr. Arsenault's request for a hearing be denied and that the FDA Commissioner uphold the validity of its order to cease manufacturing. *See* FAC, Ex. 2 (Agency Decision at 2-3). In December 2012, the Commissioner denied Mr. Arsenault's request for a hearing and found that the CBER's order to cease manufacturing was properly issued. *See* FAC, Ex. 2 (Agency Decision at 13-14). There is nothing in the record to indicate that Mr. Arsenault has since challenged the Commissioner's decision.

Based on, *inter alia*, the above, Ms. Doe has filed suit against two federal officials in their official capacities only, seeking nonmonetary relief only. The specific claims raised in the FAC are as follows:

(1) Violation of Ms. Doe and Mr. Arsenault's "rights to privacy, bodily integrity and autonomy, procreative liberty, and due process in violation of the Due Process Clause of the Fifth Amendment." FAC ¶ 102; *see also* FAC ¶ 103.

(2) Violation of Ms. Doe and Mr. Arsenault's right to equal protection through the imposition of requirements on artificial insemination that are not imposed on "natural insemination." FAC ¶ 105.

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[3] According to the government, the "FDA has only once initiated enforcement action against an establishment comprised of a single individual semen donor – Arsenault." Mot. at 4.

(3) Violation of Ms. Doe and Mr. Arsenault's right of intimate association as protected by the First Amendment and the Fifth Amendment's due process clause.

(4) Violation of the Commerce Clause through regulation of artificial insemination done on a "private, uncompensated basis." FAC ¶ 115; *see also* FAC ¶ 116.

(5) Violation of the Ninth Amendment, which provides that "[t]he enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people." U.S. Const., amend. IX.

(6) Violation of the Tenth Amendment, which provides that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. Const., amend. X.

(7) Violation of the APA because the regulations – which cover "private, noncommercial acts of conception accomplished by consenting adults through artificial insemination in the privacy of their homes" – are in excess of the agency's authority under the PSHA. FAC ¶ 124; *see also* FAC ¶ 125.

(8) Violation of the APA because the Commissioner's decision to uphold CBER's order to cease manufacturing is, *inter alia*, arbitrary and capricious.

Ms. Doe claims to be making both facial and as applied challenges to the regulations. *See, e.g.*, FAC ¶ 5 (alleging that the regulations "are unconstitutional, facially and as applied to Ms. Doe, to the extent that they operate to regulate noncommercial, sexually intimate choices and activity").

II. DISCUSSION

As noted above, the government makes two basic arguments in its papers: (1) that the Court should decline jurisdiction over Ms. Doe's case based on a lack of prudential standing and (2) that, even if there is no standing problem, for each of the asserted constitutional claims, Ms. Doe has failed to state a claim for relief. Because the Court agrees that prudential standing is lacking, it need not address the latter argument presented by the government.

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A. Constitutional Standing

As a preliminary matter, the Court notes that the government claims to make a challenge to prudential standing only, and not to constitutional (Article III) standing.[4] Because the government does not expressly contest constitutional standing, and because Ms. Doe's allegations in the FAC are sufficient to make out at least a prima facie case of constitutional standing, the Court addresses only the issue of prudential standing.

B. Legal Standard for Prudential Standing

> "[P]rudential standing . . . embodies judicially self-imposed limits on the exercise of federal jurisdiction." These limits include "the general prohibition on a litigant's raising another person's legal rights, the rule barring adjudication of generalized grievances more appropriately addressed in the representative branches, and the requirement that a plaintiff's complaint fall within the zone of interests protected by the law invoked."

Doran v. 7-Eleven, Inc., 524 F.3d 1034, 1044 (9th Cir. 2008) (internal quotation marks omitted).

While constitutional standing is evaluated under Federal Rule of Civil Procedure 12(b)(1), prudential standing is evaluated under Rule 12(b)(6). In *The Cetacean Community v. Bush*, 386 F.3d 1169 (9th Cir. 2004), the Ninth Circuit held that, where statutory standing (as opposed to constitutional standing) is at issue, Rule 12(b)(6) provides the applicable legal standard. The court explained that, "[i]f a plaintiff has suffered sufficient injury to satisfy the jurisdictional requirement of Article III but Congress has not granted statutory standing, that plaintiff cannot state a claim upon which relief can be granted" and, "[i]n that event, the suit should be dismissed under Rule 12(b)(6)." *Id.* at 1175. The same reasoning applies with respect to prudential standing. Indeed, the Fifth Circuit has expressly held that, "[u]nlike a dismissal for lack of constitutional standing, which should be granted under Rule 12(b)(1), a dismissal for lack of prudential or statutory standing is properly granted under Rule 12(b)(6)." *Harold H. Huggins Realty, Inc. v. FNC, Inc.*, 634 F.3d 787,

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[4] A prudential standing challenge may be made even where there is no constitutional standing problem. *See Fleck & Assocs. v. City of Phoenix*, 471 F.3d 1100, 1105 (9th Cir. 2006) (noting that "exceptions to the prudential rule presuppose a litigant who has *already* met the constitutional requirements") (emphasis in original); *Planned Parenthood of Id., Inc. v. Wasden*, 376 F.3d 908, 917 (9th Cir. 2004) (stating that, "[a]s a prudential matter, even when a plaintiff has Article III standing, we ordinarily do not allow third parties to litigate on the basis of the rights of others").

795 n.2 (5th Cir. 2011); *see also Ross v. Deutsche Bank Nat'l Trust Co.*, No. 12-10586-WGY, 2013 U.S. Dist. LEXIS 47056, at *7 (D. Mass. Mar. 27, 2013) (stating that a "Rule 12(b)(1) motion [that is] premised on a challenge to prudential standing . . . is properly reviewed under Rule 12(b)(6)"); *Gentges v. Trend Micro Inc.*, No. C 11-5574 SBA, 2012 U.S. Dist. LEXIS 94714, at *11 n.3 (N.D. Cal. July 9, 2012) (stating that, "[w]hile Article III standing may be raised in a Rule 12(b)(1) motion, questions of prudential standing must be raised in a Rule 12(b)(6) motion").

C. Claims Asserted by Ms. Doe

In the instant case, the government argues that there is a prudential standing problem because "[Ms.] Doe's alleged claim of injury is indirect and wholly rests on FDA's application of Part 1271 to a [third] party not before this Court," *i.e.*, Mr. Arsenault. *See* Mot. at 7-8.[5]

Ms. Doe's FAC, as currently pled, seems to assert two kinds of claims: (1) claims brought on behalf of Mr. Arsenault and (2) claims brought on behalf of Ms. Doe. While, in her opposition brief, Ms. Doe does not contend that she is making any claims on Mr. Arsenault's behalf, the FAC as pled certainly suggests such. *See, e.g.*, FAC ¶¶ 101-03, 107-09, 111-12, 116, 119, 122 (alleging that the regulations and the Commissioner's decision upholding CBER's order violated both Ms. Doe *and* Mr. Arsenault's constitutional rights).

1. Claims Brought on Mr. Arsenault's Behalf

To the extent Ms. Doe is bringing claims on the behalf of Mr. Arsenault (*i.e.*, claims based on his rights only), there is clearly a prudential standing issue. While a plaintiff is allowed to bring claims on behalf of a third party in limited circumstances, Ms. Doe has failed to establish that her situation falls within those limited circumstances.

"To demonstrate third party standing, a plaintiff must show his own injury, a close relationship between himself and the parties whose rights he asserts, and the inability of the parties to assert their own rights." *McCollum v. California Department of Corrections & Rehabilitation*, 647 F.3d 870, 879 (9th Cir. 2011). In the case at bar, the government has not contested that Ms. Doe

[5] Contrary to what Ms. Doe suggests, the government is not making a prudential standing argument based on the zone-of-interests test. That is a different strand of prudential standing that the government is not asserting. *See* Reply at 6.

has suffered an injury. (Indeed, the government has not challenged Ms. Doe's constitutional standing, which requires that she have an injury in fact.) The only questions remaining, therefore, are whether there is a close relationship between Ms. Doe and Mr. Arsenault and whether Mr. Arsenault is unable to assert his own rights.

The Ninth Circuit has indicated that the close relationship requirement may be satisfied where the litigant "'is fully, or very nearly, as effective a proponent of the right as the [third party].'" *Voigt v. Savell*, 70 F.3d 1552, 1564-65 (9th Cir. 1995); *see also United States v. 100,348.00 in United States Currency*, 354 F.3d 1110, 1127 (9th Cir. 2004) (stating that "[a] third party may litigate another person's rights only if 'the third party can reasonably be expected properly to frame the issues and present them with the necessary adversarial zeal'"). For example, in *Wauchope v. United States Department of State*, 985 F.2d 1407 (9th Cir. 1993), the court held that the plaintiffs had third-party standing to assert their mothers' equal protection rights in challenging the constitutionality of a statute that granted citizenship to foreign-born children of United States citizen fathers, but not to those born of United States citizen mothers, because the plaintiffs' "interests coincide[d] with those of their mothers and [were] equally as intense." *Id.* at 1411.

According to the government, Ms. Doe and her donor do not have the necessary closeness because her interests and his are not parallel and are potentially in conflict. *See* Mot. at 8. For example, at the hearing, the government noted that there could be a conflict with respect to the ability to bear the costs of compliance with the regulation and with respect to whether Mr. Arsenault is an establishment for purposes of the regulation. In particular, Mr. Arsenault appears not to have contested the fact that he is an "establishment" within the meaning of the regulations, whereas Ms. Doe appears to challenge the application of all the regulations to Mr. Arsenault. Mr. Arsenault may have desired to forgo an argument that he is not an "establishment" not only because such an argument appears factually meritless but also because such a designation could lend him credibility and enhance the marketing of his services.

The Court need not resolve this issue, however, because, even if there were an alignment of interests between Ms. Doe and Mr. Arsenault, and thus a close relationship between a litigant and a third party, the ability of the third party to assert his own rights must still be considered as "the

reasons for requiring persons to assert their own rights will generally still apply." *Singleton v. Wulff*, 428 U.S. 106, 116 (1976). *See, e.g.*, *id.* at 113-14 (noting that, potentially, "holders of [the asserted] rights either do not wish to assert them, or will be able to enjoy them regardless of whether the in-court litigant is successful or not"; adding that, "third parties themselves usually will be the best proponents of their own rights"). Where "there is some genuine obstacle" to a third party asserting his own rights, then "the third party's absence from the court loses its tendency to suggest that his right is not truly at stake, or truly unimportant to him, and the party who is in court becomes by default the right's best available proponent." *Id.* at 116.

Both in her papers and at the hearing, Ms. Doe failed to identify any obstacles that prevent Mr. Arsenault from bringing suit on his own behalf. Moreover, any obstacles are not otherwise facially apparent.

Accordingly, to the extent Ms. Doe brings claims solely on behalf of Mr. Arsenault, those claims are dismissed for lack of prudential standing.

2. Claims Allegedly Brought on Ms. Doe's Behalf

Ms. Doe also takes the position that the FDA regulations and the CBER order have affected her *own* constitutional rights, not just Mr. Arsenault's. However, under the facts alleged in this case, it is evident that Ms. Doe asserts no independent rights of her own that would remove this case from third-party standing analysis. Ms. Doe is not a direct target of the FDA regulations and the CBER order, and her alleged constitutional rights are derived entirely from Mr. Arsenault's alleged constitutional rights.

Absent the FDA regulations and the CBER order applied to Mr. Arsenault, Ms. Doe could not claim any limitations on her rights. Ms. Doe admits as much in her complaint. *See* SAC ¶ 88 (alleging that "[t]he reproductive rights of individual men, like Mr. Arsenault, who donate semen for artificial insemination on an uncompensated and private basis are inextricably entwined with the reproductive rights of women, such as Ms. Doe, who intend to conceive children with them"). Although Ms. Doe suggests she has broader rights independent of Mr. Arsenault's which are violated, such as her general right to procreate, her argument is specious. Nothing about the FDA regulations and the CBER order bar Ms. Doe from procreating. *Compare Skinner v. Oklahoma*, 316

U.S. 535 (1942). Nor is she barred from procreating via artificial insemination or doing so in the privacy of her own home without a medical intermediary as she asserts. She can obtain semen from a donor who is not an establishment. She can also obtain semen from a directed reproductive donor, who like Mr. Arsenault, is an establishment, so long as the donor complies with the FDA regulations regarding, *e.g.*, testing. Thus, Ms. Doe is not impeded from exercising any general constitutional right to procreate or even a more specific right (if it exists) to procreate via artificial insemination. The only thing Ms. Doe is deprived of is the right to have Mr. Arsenault's child specifically through a "commercial" (*i.e.*, nonintimate) relationship. Indeed, had Mr. Arsenault complied with the FDA regulations, Ms. Doe's interest in artificial insemination by Mr. Arsenault would not be impeded whatsoever. This situation stands in stark contrast to cases where the deprivation of rights was far more generalized. *See, e.g., Roe v. Wade*, 410 U.S. 113 (1973) (addressing a state statute that made it a crime to procure an abortion (with one exception), which implicated a woman's decision whether to terminate a pregnancy); *Skinner*, 316 U.S. at 535 (addressing forced sterilization which impaired right to procreate).

Accordingly, Ms. Doe asserts no independent rights personal to her. Where the rights asserted are actually those of a third party, the prudential standing analysis of third-party standing applies. In this regard, *McCollum* is a particularly instructive case. In *McCollum*, the plaintiff – a chaplain for the Wiccan religion – challenged a paid chaplaincy program maintained by the California Department of Corrections and Rehabilitation because the program employed only Protestant, Catholic, Jewish, Muslim, and Native American clergy to serve the inmate population. One of the plaintiff's claims was that his *own* free exercise rights were violated because " his access to his prison congregation as an approved volunteer chaplain was impeded." *McCollum*, 647 F.3d at 879. The Ninth Circuit held that, in spite of the claim that his own rights were violated, the plaintiff lacked prudential standing because the plaintiff was really "assert[ing] not his own rights, but the free exercise rights of prison inmates. [The plaintiff's] right to minister to Wiccan inmates is *derivative* of the inmates' rights to have access to a minister of their faith, and the inmates' rights in that vein are not absolute." *Id.* (emphasis added). In the instant case, Ms. Doe's rights are similarly derivative of Mr. Arsenault's.

For the reasons stated above, the fact that Mr. Arsenault was free to assert his own rights upon which Ms. Doe's asserted rights are derived defeats Ms. Doe's standing to prosecute the instant case. *Cf. Mainstreet Organization of Realtors v. Calumet City*, 505 F.3d 742, 745-47 (7th Cir. 2007) (noting that "[o]ften the harm from a harmful act will ramify far beyond [the direct] victim" and that, where "there is no hindrance to the primary victims' enforcing their rights, there is no reason to allow the [remote victims] into the litigation arena").

III. CONCLUSION

The underlying justifications for the general rule prohibiting third-party standing are twofold: (1) "[T]he courts should not adjudicate [the] rights [of third parties] unnecessarily, and it may be that in fact the holders of those rights either do not wish to assert them, or will be able to enjoy them regardless of whether the in-court litigant is successful or not," and (2) "third parties themselves usually will be the best proponents of their own rights" and courts "should prefer to construe legal rights only when the most effective advocates of those rights are before them." *Singleton*, 428 U.S. at 113-14. These justifications – particularly the latter – are implicated in the instant case given that Ms. Doe is only indirectly affected by the FDA regulations and the CBER order and her rights asserted herein are entirely derivative of Mr. Arsenault's. While there are

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situations where third-party standing is permissible,[6] this is not one of them. Accordingly, the Court concludes that Ms. Doe lacks prudential standing to proceed with this litigation.

The government's motion to dismiss is granted.

This order disposes of Docket No. 36.

IT IS SO ORDERED.

Dated: July 16, 2013

EDWARD M. CHEN
United States District Judge

[6] For example, in *Warth v. Seldin*, 422 U.S. 490 (1975), the Supreme Court noted that it had "allowed standing to litigate the right of third parties when enforcement of the challenged restriction against the litigant would result indirectly in the violation of third parties' rights." *Id.* at 510 (emphasis added; citing *Griswold v. Connecticut*, 381 U.S. 479 (1965) (holding that medical providers, who were convicted as accessories for giving married persons information and medical advice on how to prevent conception and prescribing a contraceptive device or material for wife's use, had standing to raise the constitutional rights of the married people with whom they had a professional relationship), and *Doe v. Bolton*, 410 U.S. 179 (1973) (holding that doctors had standing to challenge a state law that proscribed abortion with limited exceptions and that provided for certain procedural requirements before an abortion could take place)). Here, the FDA regulations and the CBER order have no application against Ms. Doe at all, and therefore this case is not comparable to either *Griswold* or *Doe*.